K043434

FEB 1 6 2005

510(k) Summary

Device Proprietary Name:	OsteoMed Pediatric Intraoral Mandibular Distraction System
Device Common Name:	Intraoral Distractor
Classification Name:	MQN, External Mandibular Fixator and/or Distractor
Name of Submitter:	OsteoMed L. P. 3885 Arapaho Road Addison, Texas 75001 Phone: (972) 677-4600 Fax: (972) 677-4601
Contact Person:	Dawn T. Holdeman
Date Prepared:	December 7, 2004

Summary:

This submission describes the OsteoMed Pediatric Intraoral Mandibular Distraction System indicated for use as a bone stabilizer and lengthening (and/or transport) device when correction of congenital deficiencies or post traumatic defects of the mandible (including ramus, body, symphisis) require gradual distraction. This system is intended for use in pediatric population for children under 4 years of age including infants and neonates. The OsteoMed Pediatric Intraoral Mandibular Distraction System is intended for single patient use only.

The OsteoMed Pediatric Intraoral Mandibular Distraction System is a subcutaneous bone distractor. It features various curved and straight bars, activated with a threaded wire, that have plates that are fixed to bone via 1.2mm bone screws. The distractor is available in right and left versions. The threaded wire is activated by a hex driver and is capable of distraction lengths of up to 35mm.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the KLS-Martin Zurich Pediatric Distraction System (K010139), the KLS-Martin Micro Mandibular Distractor and the OsteoMed Intraoral Mandibular Distraction System (K013618).

Due to the similarity of materials and design to both pre-enactment and post-enactment devices, OsteoMed believes that the OsteoMed Pediatric Intraoral Mandibular Distraction System does not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 2005

Ms. Dawn T. Holdeman
Regulatory Affairs and Document Control
OsteoMed L.P.
3885 Arapaho Road
Addison, Texas 75001

Re: K043434
Trade/Device Name: OsteoMed Pediatric Intraoral Mandibular Distraction System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: December 10, 2004
Received: December 13, 2004

Dear Ms. Holdeman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043434

Indications for Use

510(k) Number (if known): K043434

Device Name: OsteoMed Pediatric Intraoral Mandibular Distraction System

Indications for Use:

Intended as a bone stabilizer and lengthening (and/or transport) device when correction of congenital deficiencies or post traumatic defects of the mandible (including ramus, body, symphisis), require gradual distraction.

This system is intended for use in pediatric population for children under 4 years of age including infants and neonates.

The OsteoMed Pediatric Intraoral Mandibular Distraction System is intended for single patient use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K043434